

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Reiko Irie et al. Art Unit : 1644
Patent No. : 7,709,615 Examiner : Ilia I. Ouspenski
Issue Date : May 4, 2010 Conf. No. : 1468
Serial No. : 10/564,665
Filed : September 21, 2006
Title : IGM PRODUCTION BY TRANSFORMED CELL AND METHOD OF
QUANTIFYING THE SAME

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)

Patentees hereby request reconsideration of the Patent Term Adjustment (PTA) accorded the above-referenced patent. In good faith and candor, Patentees submit that the currently calculated total PTA of 610 days may be longer than appropriate and should instead be calculated as 490 days.

REMARKS

(1) Measuring Overlap of “A Delay” and “B Delay”

“A Delays” are defined as delays by the U.S. Patent and Trademark Office (PTO) under 35 U.S.C. § 154(b)(1)(A), which guarantees prompt PTO response. “B Delays” are defined as delays by the PTO under 35 U.S.C. § 154(b)(1)(B), which guarantees no more than three year application pendency. To the extent that the periods of delay overlap, the period of any term adjustment shall not exceed the actual number of days the issuance of the patent was delayed. 35 U.S.C. § 154(b)(2)(A).

(2) Measuring “B Delay” for a National Stage Filing under 35 U.S.C. § 371

Patentees respectfully submit that the Office did not apply the proper standard for determining the period of “B Delay” under 35 U.S.C. § 154(b)(1)(B). It is Patentees’ understanding that for purposes of calculating “B Delay,” the Office measured application pendency as beginning on January 17, 2006, the date that is 30 months and 2 days from the

CERTIFICATE OF MAILING BY EFS-WEB FILING

I hereby certify that this paper was filed with the Patent and Trademark Office using the EFS-WEB system on this date: July 6, 2010.

priority date of the international application (i.e., two days after the date on which the national stage of the international application commenced under 35 U.S.C. § 371(b)).

The term of a patent shall, under certain circumstances, be extended if the Office fails to issue a patent within three years after the “actual filing date” of the application.

(B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY.

Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States ... the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued. 35 U.S.C. § 154(b)(1)(B). (emphasis added)

37 C.F.R. § 1.702(b) explains the meaning of the term “actual filing date” as used in 35 U.S.C. § 154(b)(1)(B). As detailed below, PTO delay for a national stage application begins if the Office fails to issue a patent within three years after the date the national stage “commenced under 35 U.S.C. 371(b) or (f).”¹

(b) *Failure to issue a patent within three years of the actual filing date of the application.* Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application, but not including... 37 C.F.R. § 1.702(b). (emphasis added)

35 U.S.C. §§ 371(b) and (f) refer to the time when a national stage application “commences.”

(b) Subject to subsection (f) of this section, the national stage shall commence with the expiration of the applicable time limit under article 22 (1) or (2), or under article 39 (1)(a) of the treaty. 35 U.S.C. § 371(b). (emphasis added)

(f) At the express request of the applicant, the national stage of processing may be commenced at any time at which the application is in order for such purpose and the applicable requirements of subsection (c) of this section have been complied with. 35 U.S.C. § 371(f).

¹ Consistent with 37 C.F.R. § 1.702(b), MPEP § 2730 states that “[i]n the case of an international application, the phrase ‘actual filing date of the application in the United States’ [as used in 35 U.S.C. § 154(b)(1)(B)] means the date the national stage commenced under 35 U.S.C. 371(b) or (f).”

35 U.S.C. § 371(f) relates to the situation where an applicant files an express request for early processing of an international application. In the absence of filing such a request, the U.S. national stage commences under the provisions of 35 U.S.C. § 371(b), i.e., with the expiration of the applicable time limit under article 22(1) or (2), or under article 39(1)(a) of the treaty. The term "the treaty" refers to "the Patent Cooperation Treaty done at Washington, on June 19, 1970." See 35 U.S.C. § 351(a).

The articles of the Patent Cooperation Treaty cited in 35 U.S.C. § 371(b) are reproduced below.

Article 22

Copy, Translation, and Fee, to Designated Offices

- (1) The applicant shall furnish a copy of the international application (unless the communication provided for in Article 20 has already taken place) and a translation thereof (as prescribed), and pay the national fee (if any), to each designated Office not later than at the expiration of 30 months from the priority date. Where the national law of the designated State requires the indication of the name of and other prescribed data concerning the inventor but allows that these indications be furnished at a time later than that of the filing of a national application, the applicant shall, unless they were contained in the request, furnish the said indications to the national Office of or acting for the State not later than at the expiration of 30 months from the priority date. (emphasis added)
- (2) Where the International Searching Authority makes a declaration, under Article 17(2)(a), that no international search report will be established, the time limit for performing the acts referred to in paragraph (1) of this Article shall be the same as that provided for in paragraph (1).

Article 39

Copy, Translation, and Fee, to Elected Offices

- (1) (a) If the election of any Contracting State has been effected prior to the expiration of the 19th month from the priority date, the provisions of Article 22 shall not apply to such State and the applicant shall furnish a copy of the international application (unless the communication under Article 20 has already taken place) and a translation thereof (as prescribed), and pay the national fee (if

any), to each elected Office not later than at the expiration of 30 months from the priority date. (emphasis added)

“The applicable time limit” referred to in Patent Cooperation Treaty articles 22(1), 22(2), and 39(1)(a) is “the expiration of 30 months from the priority date.” As a result, “the expiration of 30 months from the priority date” is the time at which the U.S. national stage commences under the provisions of 35 U.S.C. § 371(b). This same conclusion as to the timing for commencement of the U.S. national stage is also summarized in MPEP § 1893.01.

Subject to 35 U.S.C. 371(f), commencement of the national stage occurs upon expiration of the applicable time limit under PCT Article 22(1) or (2), or under PCT Article 39(1)(a). See 35 U.S.C. 371(b) and 37 CFR 1.491(a). PCT Articles 22(1), 22(2), and 39(1)(a) provide for a time limit of not later than the expiration of 30 months from the priority date. Thus, in the absence of an express request for early processing of an international application under 35 U.S.C. 371(f) and compliance with the conditions provided therein, the U.S. national stage will commence upon expiration of 30 months from the priority date of the international application. Pursuant to 35 U.S.C. 371(f), the national stage may commence earlier than 30 months from the priority date, provided applicant makes an express request for early processing and has complied with the applicable requirements under 35 U.S.C. 371(c). MPEP § 1893.01.
(emphasis added)

In view of the foregoing, the “actual filing date” of a U.S. national stage application filed under 35 U.S.C. § 371, for purposes of calculating “B Delay” under 35 U.S.C. § 154(b)(1)(B) and 37 C.F.R. § 1.702(b), is the date that is 30 months from the priority date of the international application.²

In the instant patent, the priority date of the international application is July 15, 2003. As such, the date that is 30 months from the priority date of the international application is January 15, 2006, not January 17, 2006, as apparently calculated by the Office.

² In contrast to reliance on “the expiration of 30 months from the priority date” for measuring “B Delay,” the beginning of the relevant period for purposes of calculating “A Delay” is the date on which an international application fulfills the requirements of 35 U.S.C. § 371. See 35 U.S.C. § 154(b)(1)(A)(i)(II) and 37 C.F.R. § 1.702(a)(1).

REVIEW OF PATENT TERM ADJUSTMENT CALCULATION

“A Delay”

A first PTO action was due on or before November 21, 2007 (the date that is fourteen months after September 21, 2006, the date on which the application fulfilled the requirements of 35 U.S.C. § 371). The PTO mailed the first non-final Office Action on July 9, 2008, thereby according a PTO Delay of 231 days. Patentees do not dispute the PTO's calculation for this “A Delay” from November 22, 2007 (the day after the date that is four months after the date on which a response to Office Action was filed), to July 9, 2008. See 37 C.F.R. §§ 1.702(a)(1) and 1.703(a)(1).

In view of the period of “A Delay” detailed above, the total “A Delay” for this patent should be calculated as 231 days.

“B Delay”

The present application is a national stage filing under 35 U.S.C. § 371 of international application number PCT/JP2004/010444, filed July 15, 2004, which claims the benefit of priority of United States Provisional Application No. 60/487,333, filed July 15, 2003.

The national stage for the present application “commenced” under the provisions of 35 U.S.C. § 371(b), i.e., upon expiration of 30 months from the priority date of the international application.³ As a result, the date on which the national stage commenced was January 15, 2006 (i.e., 30 months from the priority date of July 15, 2003).

The period beginning on January 16, 2009 (the day after the date that is three years after January 15, 2006, the date that the national stage commenced), and ending May 4, 2010 (the date the patent was issued), is 474 days in length.

“B Delay” may not include the number of days in the period beginning on the date on which a Request for Continued Examination was filed and ending on the date the patent was issued. In the present application, no Request for Continued Examination was filed. See 37 C.F.R. §§ 1.702(b)(1) and 1.703(b)(1).

³ A complete request for early processing under 35 U.S.C. § 371(f) was not filed with the present application.

In view of the periods of "B Delay" detailed above, the total "B Delay" for this patent should be calculated as 474 days. The PTO calculated 472 days of delay for issuance of a patent more than three years after filing. Patentees respectfully submit that the PTO's calculation of this "B Delay" is incorrect and that the correct PTO Delay for issuance beyond three years from filing is 474 days. See 37 C.F.R. §§ 1.702(b) and 1.703(b).

Overlap of "A Delay" and "B Delay"

As detailed above, "A Delay" accumulated during the following period:

November 22, 2007, to July 9, 2008.

As detailed above, "B Delay" accumulated during the following period:

January 16, 2009, to May 4, 2010.

As such, the periods of "A Delay" and "B Delay" do not overlap (i.e., occur on the same calendar day).

Applicant Delay

A reply to a Notification of Missing Requirements was due on or before May 22, 2006 (the date that is three months after February 22, 2006, the date on which the Notification of Missing Requirements was mailed). Patentees filed a response to the Notification of Missing Requirements on September 21, 2006. No Applicant Delay was accorded for this reply; however, in good faith and candor, Patentees respectfully submit that the late response to the Notification of Missing Requirements should have been accorded a total Applicant Delay of 122 days for delay from May 23, 2006, to September 21, 2006. See 37 C.F.R. § 1.704(b).

A reply to an Office Action was due on or before July 20, 2009 (the date that is three months after April 20, 2009, the date on which the Office Action was mailed). Patentees filed a response to the Office Action on October 19, 2009, thereby according an Applicant Delay of 91 days. Patentees do not dispute the PTO's calculation for this Applicant Delay from July 21, 2009 (the day after the date that is three months after the date on which the Office Action was mailed), to October 19, 2009. See 37 C.F.R. § 1.704(b).

Patentees filed an Information Disclosure Statement on October 21, 2009, subsequent to a reply filed on October 19, 2009. Patentees were accorded a delay of 2 days for a supplemental

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response. Patentees do not dispute the PTO's calculation for this Applicant Delay from October 20, 2009, to October 21, 2009. See 37 C.F.R. § 1.704(c)(8).

In view of the periods of Applicant Delay detailed above, the total Applicant Delay for this patent should be calculated as 215 days (i.e., the sum of 122 days, 91 days, and 2 days).

Terminal Disclaimer

This patent is not subject to a terminal disclaimer.

Conclusion

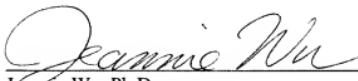
In consideration of the events described above, Patentees believe the PTA calculation of 610 days is incorrect. As such, Patentees respectfully request reconsideration of the PTA in the following manner:

- 1) Total PTO Delay should be calculated as 705 days (i.e., the sum of 231 days of "A Delay" and 474 days of "B Delay");
- 2) Total Applicant Delay should be calculated as 215 days (i.e., the sum of 122 days, 91 days, and 2 days); and
- 3) Total PTA should be calculated as 490 days.

As Patentees are herein advising the Office of errors that, when corrected, reduce the total PTA calculation, no fee is believed due. If this is incorrect and a fee is in fact due, please apply any required charges or credits to Deposit Account No. 06-1050, referencing attorney docket number 14875-0155US1.

Respectfully submitted,

Date: July 6, 2010


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